REMARKS

Reconsideration of the application in view of the following remarks is requested. Entry of the remarks is appropriate as it places the case in better condition for appeal.

I. The Rejection of Claims 1-16, 18-20 and 27-38 under 35 U.S.C. 112, 1st ¶

Claims 1-16, 18-20 and 27-38 are rejected under 35 U.S.C. 112 as lacking enablement. The Examiner states, *inter alia*, that although the claims are enabled for methods of contacting either dispersible materials with water, oil or aqueous liquids; or fully water soluble particulate materials contacted with oil; the specification does not reasonably provide enablement for making particulate compositions by contacting a particulate starting material that is fully water soluble to form a mixture that results in a particulate composition. Applicants traverse this rejection.

It is well settled that "[t]he first paragraph of section 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance." *In re Marzocchi*, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971). Moreover, "a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of section 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 169 U.S.P.Q. at 369.

Moreover, "[a]ny assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed." *In re Dinh-Nguyen*, 181 U.S.P.Q. 46, 47 (C.C.P.A. 1974). Thus, the burden is upon the Patent Office to set forth reasonable grounds in support of its contention that a claim reads on inoperable subject matter). See *In re Stark*, 172 U.S.P.Q. 402, 406 n. 4 (C.C.P.A. 1972).

“The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art ... The test is not quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the

direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed ..." *Ex parte Jackson*, 217 U.S.P.Q. 804 (Bd. Pat. App. 1982).

Applicants submit that Applicants' claimed invention is enabled by the specification. The specification discloses fully water soluble particulate starting material and explains how it is applied in the methods of the present disclosure. For example, the specification at page 2, lines 18-19 provides basis for water soluble particles. More specifically the specification states "Furthermore the particles are readily dispersible or soluble in water, preferably **fully soluble in water**." See page 2, lines 18-19. (Emphasis added in bold).

Importantly, the specification at page 5 provides:

> For many particles it is desirable that the particles are readily dispersible or soluble in water and often it is desired to have fully soluble particles, e.g. enzymes particles and inert particles used as carrier materials or seeds which are often used in products where it is desirable that the product is readily dispersible or soluble in water and often fully soluble. **Therefore it may be important that the materials used to produce said particles are readily dispersible or soluble in water and preferably fully soluble in water.** We have found that the present invention is a very cost effective way of preparing water soluble inert particles with higher particle strength than compared to ordinary non-pareil seeds.

Moreover, page 8 provides:

> "Water soluble" particulate materials or fractions of materials in the context of the present invention are understood to be particulate materials of fractions of materials of which at least 50 g/l and more particularly, at least 80 g/l dissolve in water at a temperature of 30°C.

Further, under the section "Particulate starting materials" the specification clearly states: "In a particular embodiment of the present invention the particulate material is water soluble." See page 8, line 10.

Importantly, the present application discloses on page 12, lines 20-27:

> The amount of liquid added to the high shear treatment is of great importance. If a too high amount of liquid is added to the particulate material, the composition exposed to the high shear process will become too sticky and the particulate material will start agglomerating. In a particular embodiment of the present invention the amount of liquid added to the high shear treatment is not exceeding 20 % by weight, in a more particular embodiment the amount of liquid added to the high shear treatment is not exceeding 15% by weight, in an even more particular

embodiment of the present invention the amount of liquid added to the high shear treatment is not exceeding 10 % by weight.

Accordingly, Applicants' specification adequately describes how to carry out the methods wherein the particulate starting materials is fully soluble in water when water or aqueous liquid is the liquid. One of ordinary skill in the art knows and understands that one may contact a constituent characterized as "fully water soluble" such that the constituent does not go entirely and immediately into solution. While some experimentation might be necessary to ensure that the particles do not go entirely into solution using a particulate starting material which is fully water soluble, such experimentation would not be undue and certainly would not require ingenuity beyond that expected of one of ordinary skill in the art. Certainly, there is no evidence of record to the contrary.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

II: The Rejection of Claims 1-16, 18-20 and 27-38 under 35 U.S.C. 112, 2nd ¶

In the Office action, claims 1-16, 18-20 and 27-38 were rejected under 35 U.S.C. 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner contends: 1) Applicants preamble in the independent claims is inconsistent with the scope of the claimed subject matter . .. 2) it is unclear how a particulate starting material that is fully water soluble material and is mixed with liquid to form a mixture can possibly result in a particulate composition without some other processing step and 3) it is unclear how "fully water soluble" is defined. Applicants respectfully traverse.

The essential inquiry for determining indefiniteness is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness must be analyzed in light of the claim interpretation that would be given by one possessing the ordinary skill in the pertinent art at the time the invention was made. (M.P.E.P. 2173.02) One of ordinary skill in the art would certainly understand that the phrase "fully water soluble" means that particulate starting material is made of constituent(s) characterized as fully water soluble. One of skill in the art would further understand how to identify and obtain fully water soluble constituents

especially in light of the straightforward understanding of water soluble. The Examiner's confusion is difficult to understand. The Examiner's statement that it is unclear how a particulate starting material that is fully water soluble material and is mixed with liquid to form a mixture can possibly result in a particulate composition without some other processing step suggests that one of skill in the art would not find it possible to contact constituents characterized as fully water soluble with water and not have the entire constituent go into solution. However, the specification clearly sets out a definition of water soluble and explains the purpose of contacting the constituents with water. See e.g., page 2 lines 5-20.

> The present invention is useful whenever it is desired to improve particle strength and/or smoothness of a composition of particles. The high shear treatment destroys the weakest particles of the particulate starting material to be improved are. Particles for which this invention is of interest may be particles comprising active compounds in particular enzyme containing granules. We have further discovered that said process is useful to produce tough smooth inert particle fractions to be used as carrier materials, cores or seeds in a number of applications, within pharmaceutical industry, baking industry, candy industry, food industry, feed industry, fertilizer industry etc. Inert particles used as carrier materials, cores or seeds are known e.g. from the so called non-pareil seeds, which are characterised by spherical particles that have been prepared by agglomeration. The inert particles of the present invention differ from ordinary non-pareil seeds by not being agglomerated into particles but comprise a dense homogenous matrix optionally covered with a layer of binder-matrix. Furthermore, this preparation method is a much more cost effective production method compared to the production method of non-pareil seeds. Furthermore the particles are readily dispersible or soluble in water, preferably fully soluble in water.

Importantly, the present application also discloses on page 12, lines 20-27:

> The amount of liquid added to the high shear treatment is of great importance. If a too high amount of liquid is added to the particulate material, the composition exposed to the high shear process will become too sticky and the particulate material will start agglomerating. In a particular embodiment of the present invention the amount of liquid added to the high shear treatment is not exceeding 20 % by weight, in a more particular embodiment the amount of liquid added to the high shear treatment is not exceeding 15% by weight, in an even more particular embodiment of the present invention the amount of liquid added to the high shear treatment is not exceeding 10 % by weight.

Accordingly, Applicants described fully water soluble particulate starting material suitable for use in accordance with the present disclosure and these terms are clear. One

of skill in the art would further understand and characterize the resulting product as a mixture. Moreover, the claims are clear in light fo the enablement arguments made above.

Further, the preamble is clear and consistent with the explanation in this paragraph.

Claim 15 is also clear in light of the above. One of ordinary skill in the art would understand that the particles of the present disclosure can be fully water soluble and be in a saturated solution. Reconsideration is urged.

Applicants respectfully submit the claim language is clear. Reconsideration is urged.

III Acknowledgement

Applicants Acknowledge the Examiner's reference to prior art made of record and not relied upon. As these were not relied upon for any rejection, Applicants will not address these references herein.

IV: Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Should any additional fees be due the USPTO is authorized to charge the deposit account of Novozymes North America, Inc, i.e., Deposit Account No. 50-1701.

Respectfully submitted,

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